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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,925	03/10/2004	Wumin Li	AM 101333	3270

25291 7590 11/10/2005

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,925	LI ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on August 8, 2005 is acknowledged. Claims 20-21 are pending and under consideration. Claims 1-19 have been withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

1. Applicant's election with traverse of Group II claims 20-21 is acknowledged. The traversal is on the ground that a) the vaccine composition (Group I) and the method of using it (Group II) are directly connected and unified as a final product and its intended use, b) the vaccine composition of claims 1-19 comprises an inactivated or killed *E. coli* O157:H7 bacterin in combination with a metabolizable oil and optionally a pharmaceutically acceptable carrier, c) the composition is ready for immunization and safety in treating animals in the method of claims 20-21 for reducing the shedding of *E. coli* O157:H7, d) inactivated or killed bacterin formulations can not be used for protein expression and e) there is no statutory prohibition against claims drawn to both product and process of use residing in the same issued patent.

This argument has been considered, but is not found persuasive. Claims 1-19 are directed to a composition and claims 20-21 are directed to a method of preventing. These are different statutory classes of invention and MPEP § 806.05(f) states that these inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process. The method for reducing the shedding of *E. coli* O157:H7 can be accomplished by administering an antibiotic. In the case at hand the examiner has averred that the product as claimed can be used in a different way. The examiner has further established a primae facie case of a burden by establishing a different classification for these two different statutory groups of invention.

The requirement is still deemed proper and is therefore made **FINAL.**

Objections Withdrawn

2. In view of applicant's response, the objections to the specification and to claim 21 are withdrawn.

Rejections Withdrawn

3. In view of applicant's response, the rejection under 35 U.S.C. 112 first paragraph is withdrawn.

Rejections Maintained

4. The rejection of claim 20 under 35 U.S.C. 102(b) is maintained for the reasons of record (page 5).

The rejection was on the ground that Finlay et al discloses compositions and methods for stimulating an immune response against *Escherichia coli* (EHEC). Finlay et al provide a vaccination schedule effective to reduce EHEC shedding by a ruminant (0024), as well as a method for reducing shedding of EHEC (0039). In certain embodiments, the EHEC is EHEC O157:H7. Finlay et al disclose a method comprising administering to the mammal a therapeutically effective amount of a composition comprising EHEC O157:H7. In addition the mammal is a human or a ruminant, such as a bovine subject. The composition further comprises an immunological adjuvant, such as an oil-in-water emulsion which comprises e.g., a mineral oil (0036). The composition and method of Finlay is the same as the claimed composition and method. Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that a) every element of the claimed invention must be identically described in the cited reference of Finlay et al, b) the reference describes compositions that employ the cell culture supernatant derived from an *E. coli* culture, c) in the process of making the concentrated supernatant, the whole cells are removed by centrifugation, d) Finlay et al only use whatever protein antigen is released in cultures since the reference bases the effectiveness and virulence of the supernatant in use as a vaccine totally on the antigenic protein content-particularly those secreted by the type III system, e) Finlay et al claim that the proteins are the major targets of the immune response in humans following infection and state that cattle do not usually mount a significant serological response against these proteins following natural exposure to the organism and f) Finlay et al do not describe the use of any bacterial vaccine, let alone Applicants'

novel inactivated or killed whole or subunit *E.coli* bacterin as a vaccine for reducing the shedding of *E. coli* O157:H7.

It is the examiners position that contrary to applicants statements Finlay et al teaches a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises treatment of the animal with a composition comprising inactivated or killed whole or subunit *E. coli* O157:H7, or mixtures thereof; a metabolizable oil adjuvant and optionally a pharmaceutically acceptable carrier. Moreover, in addition to teaching the above mentioned components Finlay et al discloses the use of immunogenic fragments, which the examiner is viewing as a subunit of *E. coli* O157:H7 (0068).

5. The rejection of claim 21 under 35 U.S.C. 103(a) is maintained for the reasons of record (page 10).

The rejection was on the ground that Finlay et al teaches compositions and methods for stimulating an immune response against *Escherichia coli (*EHEC). Finlay et al provides a vaccination schedule effective to reduce EHEC shedding by a ruminant (0024), as well as a method for reducing shedding of EHEC (0039). Finlay et al teach a method comprising administering to the mammal a therapeutically effective amount of a composition comprising EHEC O157:H7. In addition the mammal is a human or a ruminant, such as a bovine subject. The composition further comprises an immunological adjuvant, such as an oil-in-water emulsion which comprises e.g., a mineral oil (0036). The reference differs because it does not teach the limitation of a *Lactobacillus acidophilus.*

Brashears et al teaches that lactic acid bacteria were selected on the basis of characteristics indicating that the bacteria would be good candidates for a competitive exclusion product that would reduce the shedding of *Escherichia coli* O157:H7. *Lactobacillus acidophilus* among others were the most commonly identified lactic acid bacteria (title and abstract, page 355)

Finlay et al and Brashears et al are analogous in that they teach inventions related to reducing the shedding of E. coli O157 in an animal. As such it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to modify Finlay et al with Brashears et al. It would have been

expected, barring evidence to the contrary, that adding probiotics would be effective in reducing the shedding of E. coli O157 in an animal.

Applicant urges that a) the practitioner would not arrive at the claimed composition, b) the art fails to provide any suggestion or motivation of the desirability of combining the references and doing what the inventors have done, c) if Finlay et al was combined, the practitioner would still find real distinction between the claimed invention and the cited references, d) the combined references do not teach or suggest all of the critical elements of the claimed vaccine formulation and the method of using it, e) Brashears et al reports on their results from *in vitro* tests that suggest lactic acid bacteria might be a good candidate for competitive exclusion product to inhibit or eliminate *E. coli* O157:H7, f) the authors indicated future plans to use the product in cattle-feeding trials but, as of the article's publication date, they had not tried to use the product in live animals, g) the limited *in vitro* tests do no teaching to motivate the ordinary practitioner to combine the probiotics of Brashears et al with a vaccine containing the inactivated or killed whole or subunit *E. coli* O157:H7, h) *Lactobacillus acidophilus* might interfere with the immunogenic activity of the bacterial vaccine, I) the properties of the combination simply cannot be foreseen from the cited art, j) neither Finlay et al nor Brashears et al teach or imply the use of the inactivated or killed *E. coli* O157:H7 bacterin and k) the combined references totally fail to teach or suggest all claim limitations.

It is the examiner's position that applicant has argued the references individually. One cannot show nonobviousness by attacking references individually

where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, an ordinary practitioner combing the two references would have been motivated to give the fragments of *E. coli* O157:H7 supplemented with a *Lactobacillus acidophilus* to further boost an immune response and/or reduce the shedding particularly in a feed.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

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